(54) Title: DUAL-CHANNEL RF POWER DELIVERY SYSTEM
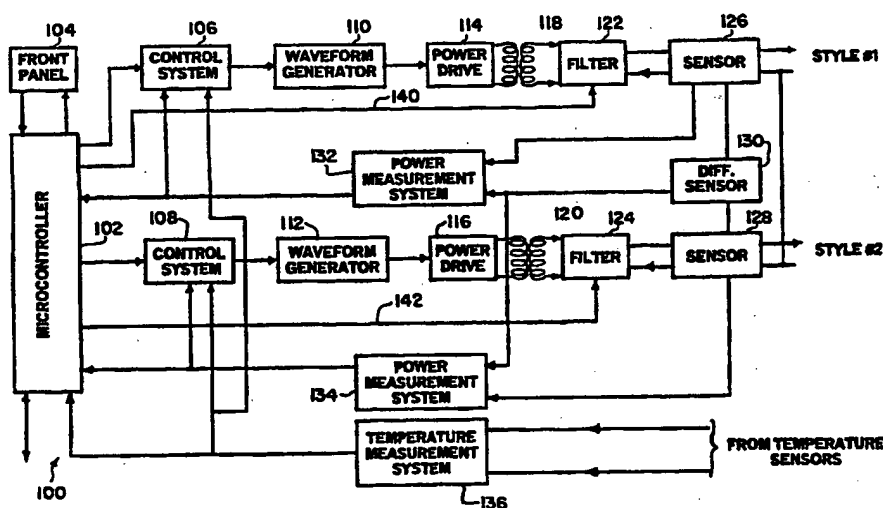
## (57) Abstract

A dual-channel RF power delivery system for applying RF energy to dual electrodes (26) of an RF ablation device with independent control of the power level, frequency, phase, and time duration of the RF energy applied to each electrode to more accurately control the ablation of a target tissue. The power delivery system supplies a first controlled RF signal having a first power level, frequency, phase, and time duration to the electrode (26) of a first flexible stylet (18) and a second controlled RF signal having a second power level frequency, phase, and time duration to the electrode (26) of a second flexible stylet (19). The difference btween the first and second power levels and the temperature of the tissue between the first stylet (18) and second stylet (19) are monitored to control the ablation of the target tissue. The supply of the first RF signal is terminated when the monitored temperature of the first stylet (18) exceeds a first predetermined value and the supply of the second RF signal is terminated when the monitored temperature of the second stylet (19) exceeds a second predetermined value.

# TITLE OF THE INVENTION

## DUAL-CHANNEL RF POWER DELIVERY SYSTEM

5

## BACKGROUND OF THE INVENTION

10     This invention relates generally to techniques for delivering radiofrequency (RF) energy for the ablation of cellular tissue and, more particularly, to techniques for delivering RF energy for the ablation of prostate tissue for the treatment of benign prosthetic hypertrophy or 15  hyperplasia (BPH).

Benign prostatic hypertrophy or hyperplasia (BPH) is one of the most common medical problems experienced by men over 50 years old. Hyperplastic enlargement of the prostate gland often leads to compression of the urethra, resulting in obstruction of the urinary tract 20  and the subsequent development of various symptoms, including frequent urination, a decrease in urinary flow, nocturia, pain, discomfort, and dribbling. The association of BPH with aging has been shown to exceed 50% in men over 50 years of age and increases in incidence to over 75% in men over 80 years of age. Symptoms of urinary tract 25  obstruction occur most frequently between the ages of 65 and 70, when approximately 65% of men in this age group have prostatic enlargement.

At the present time, there is no proven effective nonsurgical method for the treatment of BPH and the current surgical procedures are not totally satisfactory. Patients suffering from the obstructive symptoms of this disease are provided with few options: cope with the

5     symptoms (conservative management), submit to drug therapy at an early stage, or submit to one of the current surgical procedures. More than 30,000 patients per year undergo surgery in the United States for the removal of prostatic tissue. This represents less than five percent of the men exhibiting clinically significant symptoms.

10    Those suffering from BPH are often elderly men, many with additional health problems which increase the risks of surgical procedures. Surgical procedures for the removal of prostatic tissue are associated with a number of complications, including anesthesia associated morbidity, hemorrhage, coagulopathies, pulmonary emboli and

15    electrolyte imbalances. These surgical procedures can also lead to cardiac complications, bladder perforation, incontinence, infection, urethral or bladder neck stricture, retention of prostatic chips, retrograde ejaculation, and infertility. Due to the extensive invasive nature of the current surgical procedures for obstructive uropathy, the majority of

20    patients delay definitive treatment of BPH. This can lead to serious damage to structures secondary to the obstructive lesion in the prostate, such as bladder hypertrophy, hydronephrosis, and dilation of the kidney pelves. Furthermore, younger men suffering from BPH who wish to avoid risk complications, such as infertility, are often forced to avoid

25    surgical intervention. Thus the need, importance and value of improved surgical and nonsurgical methods for treating BPH is unquestionable.

High-frequency currents are used in various electrocautery procedures for cutting human tissue, especially when a bloodless incision is desired or when the operating site is not accessible with a normal

scalpel. In the latter instance, a thin instrument can be inserted through a natural body opening, such as the esophagus, intestine or urethra, for the removal of prostatic adenomas, bladder tumors or intestinal polyps. The high-frequency current is fed by a surgical probe into the tissue to

5    be cut, causing boiling and vaporization of the cell fluid so that the cell walls rupture and the tissue is separated.

Ablation of cellular tissues *in situ* has been used in the treatment of many diseases and medical conditions either alone or as an adjunct to surgical removal procedures. It is often less traumatic than surgical

10   procedures and may be the only alternative where other procedures are unsafe. Ablation devices have the advantage of using a destructive energy that is rapidly dissipated and reduced to a non-destructive level by conduction and convection forces of circulating fluids and other natural body processes.

15   Ablation devices typical utilize microwave, radiofrequency (RF), acoustical (ultrasound), or laser energy. Microwave ablation devices utilize a microwave antenna which is inserted into a natural body opening through a duct to the zone of treatment. Microwave energy is then radiated from the antenna through the duct wall into the target

20   tissue, often causing severe trauma to the duct wall. Consequently, many microwave ablation devices use a cooling system to help reduce this trauma. However, the cooling system complicates the device and requires that the device be sufficiently large to accommodate the cooling system. Laser ablation devices deliver laser energy to the target tissue

25   by "burning through" the duct wall of the urethra. Healthy cells of the duct wall and healthy tissue between the target tissue and the duct wall are also indiscriminately destroyed in the process.

## SUMMARY OF THE INVENTION

It is an object of the present invention to provide a dual-channel radiofrequency (RF) power delivery system for applying RF energy to dual electrodes of an RF ablation device with independent control of the

5    power level, frequency, phase and time duration of the RF energy applied to each electrode to more accurately control the ablation of a target tissue.

It is a further object of the present invention to provide an RF power delivery system that performs self-testing by loading each power

10   generator with an internal test load.

It is a further object of the present invention to provide calibration of temperature-measuring amplifier circuitry by switching precision reference voltage sources into the amplifier circuitry.

The present invention resides in a dual-channel RF power delivery

15   system for applying RF energy to dual electrodes of an RF ablation device with independent control of the power level, frequency, phase, and time duration of the RF energy applied to each electrode to more accurately control the ablation of the target tissue. The power delivery system supplies a first controlled RF signal having a first power level,

20   frequency, phase, and time duration to the electrode of a first flexible stylet and a second controlled RF signal having a second power level, frequency, phase, and time duration to the electrode of a second flexible stylet. The difference between the first and second power levels and the temperature of the tissue between the first and second stylets are

25   monitored to control the ablation of the target tissue. The supply of the first RF signal is terminated when the monitored temperature of the first stylet exceeds a first predetermined value and the supply of the second RF signal is terminated when the monitored temperature of the second stylet exceeds a second predetermined value. By adjusting the

frequency and/or phase of the first and second RF signals, the relative amounts of bipolar and monopolar ablation can be adjusted for accurate control of the lesion volume. The lesion volume can also be controlled by varying the deployment length of the electrodes.

5          It will be appreciated from the foregoing that the present invention represents a significant advance in the field of RF ablation devices. Other features of the present invention will become apparent from the following more detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the

10      principles of the invention.


## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded perspective view of a dual-stylet RF ablation device which is suitable for use with the RF power delivery system of the present invention;

15          Fig. 2 is a cross-sectional view of a stylet of the RF ablation device;

Fig. 3 is a cross-sectional view of the lower male anatomy;

Fig. 4 is block diagram of the RF power delivery system of the present invention;

20          Fig. 5 is a flow chart of the sequence of operations of the RF power delivery system of the present invention; and

Fig. 6 is a schematic diagram of the effects of monopolar, bipolar, and combined monopolar and bipolar ablation on lesion volume.


## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

25          As shown in Fig. 1, a dual-stylet RF ablation device includes a flexible catheter 10 which is attached to a control unit 12 by means of a connector 14. The flexible catheter 10 includes a distal tip 16 having

two stylets 18, 19, which extend outwardly from stylet ports 20, 21. The control unit 12 includes an RF power connector 22 and a thermocouple connector 24. The catheter 10 preferably has a graduated stiffness for easier insertion through a natural body opening into a body

5     duct. For example, the catheter 10 can be relatively stiff near the control unit 12 and more flexible near the distal tip 16. The catheter 10 can be constructed of an inner slotted stainless steel tube with an outer flexible sleeve, such as the catheter described in detail in copending application Serial No. 790,648 filed on August 11, 1991, the entire

10    contents of which are incorporated herein by reference. It can also be constructed of a coiled or braided wire having a bonded outer sleeve.

      Each stylet 18, 19 includes an electrode 26 enclosed within a retractable insulating sleeve 28. The stylets 18, 19 are described in detail in the copending application Serial No. 08/012,370. As shown in

15    Fig. 2, the insulating sleeve 28 has a tapered tip 30. The electrode 26 is slidably disposed in the center portion or lumen 38 of the insulating sleeve 28. A temperature sensor 42 is mounted near the tapered tip 30 of the insulating sleeve 28 for measuring the temperature of a target tissue as it is ablated.

20       Fig. 3 is a cross-sectional view of the lower male anatomy in which the catheter 10 of the RF ablation device is positioned near a prostate for treatment of benign prostatic hypertrophy or hyperplasia (BPH). As shown in Figure 3, the human male has a urethra 60 which extends from urinary bladder 62 through prostate 64 and urogenital

25    diaphragm 66. Benign prostatic hypertrophy (BPH) is a condition characterized by constriction of the prostatic urethra 60, which is caused primarily by proliferation of benign glandular and stroma cells in the prostate. The resulting glandular and stroma nodules press the wall of the urethra inwardly, restricting the urethral diameter. These nodules

also press normal tissue outwardly, which enlarges the prostate.
Traditional treatments have included removal of tissue from the urethra
wall to enlarge its lumen, either by resection or laser tissue destruction,
and heating of the prostate tissue surrounding the urethra to a

5      temperature that causes cell damage. The latter method is intended to
reduce the enlargement of the prostate and restore the urinary passage
to at least a portion of its former diameter.

The catheter 10 is extended through the urethra 60 such that the
distal tip 16 of the catheter 10 is adjacent the prostate 64. The position

10     of the distal tip 16 may be precisely controlled using an ultrasound
image, which is generated from a conventional ultrasonic transducer 72.
Ultrasonic transducer 72 is preferably inserted into rectum 74 through
anal opening 76 to a position adjacent the prostate. The transducer 72
may include temperature sensors 78, 80, 82 for measuring the

15     temperature of the rectal area in order to alert the user to any adverse
effects that may result from the heating of the prostate tissue. Sensors
78, 80, 82 may also be placed on a separate instrument that is
positioned in the rectal area after the catheter 10 is properly positioned
and the ultrasonic transducer 72 is removed. In Fig. 3, stylet 19 is

20     extended into tissue area 88 which represents tissue to be ablated.

Fig. 4 is a block diagram of a dual-channel RF power delivery
system 100 in accordance with the present invention. Power delivery
system 100 generates dual RF signals which are applied to the target
prostate tissue through the two stylets 18, 19. Power delivery system

25     100 includes a microcontroller 102, a front panel 104, parallel control
systems 106, 108, parallel dual waveform generators 110, 112, parallel
power drives 114, 116, parallel isolators 118, 120, parallel filters 122,
124, parallel sensors 126, 128, a differential sensor 130, power
measurement systems 132, 134, a temperature measurement system

136, and a foot switch (not shown). The control system 106, waveform generator 110, power drive 114, isolator 118, filter 122, and sensor 126 are connected in series and form a first power delivery channel. The control system 108, waveform generator 112, power drive 116, isolator

5       120, filter 124, and sensor 128 are connected in series and form a second power delivery channel.

The microcontroller 102 receives user input information from the front panel 104. Digital feedback information is also received from the temperature measurement system 136 and the power measurement

10      systems 132 and 134. The microcontroller 102 processes this information and generates command signals for controlling the outputs of the dual power delivery channels. The microcontroller 102 includes a conventional microprocessor, random access memory (RAM), and read only memory (ROM) (not shown). The software necessary for operation

15      of the microprocessor is typically stored in the ROM.

The front panel 104 may include different displays for displaying various types of information, such as selected RF power level, frequency, and phase of each RF signal and the measured temperatures of the various body tissues. The front panel 104 may also include a

20      keypad for entering user selectable information. The front panel 104 may also include an ON/OFF switch, RF ON/OFF switch, STAND-BY switch, POWER-UP/DOWN switch, and/or TIMER UP/DOWN switch.

Each control system 106, 108 generates control signals which control the operation of its respective waveform generator 110, 112 and

25      power drive 114, 116. Each control system 106, 108 generates control signals in response to the initial commands from the microcontroller 102 and the feedback signals from the measurement systems 132, 134 and the temperature measurement system 136. Each waveform generator 110, 112 generates an RF signal having a specific frequency, phase and

power level in accordance with the control and feedback signals. Each control system 106, 108 also includes an oscillator (not shown) for generating a clock signal that is used by its respective waveform generator for generating the RF signal.

5          Each waveform generator 110, 112 preferably generates an RF signal using a look-up table of various digital waveforms. The clock signal generated by the oscillator is used to retrieve the digital information and generate a digital RF waveform, which is converted to analog form using a digital-to-analog (D/A) converter. The various

10        digitized waveforms can be stored in the RAM in microcontroller 102 and loaded into the look-up table as needed. The RF waveforms are preferably square or sinusoidal waveforms. The RF signals generated by the waveform generators 110, 112 are amplified by power drives 114 and 116. The gain of each power drive 114, 116 is controlled by its

15        respective control system 106, 108.

          The RF ablation device is used to ablate tissues inside the human body, so steps must be taken to isolate the patient from DC and very low frequency electrical signals which may cause harm to healthy tissues or organs. Isolators 118, 120 provide isolation of the patient from these

20        potentially harmful signals. Each isolator is preferably a transformer having a primary and secondary winding and a ratio of the number of turns of the primary winding to the secondary winding of approximately one.

          Filters 122, 124 ensure that an RF signal with the desired

25        frequency is applied to each electrode 26. Each filter 122, 124 includes a bank of bandpass filters which can be digitally selected by microcontroller 102. Command signals from the microcontroller 102 are sent on lines 140, 142 to the filters 122, 124, respectively.

RF ablation of human tissue raises the temperature of the tissue to a temperature at which the tissue is destroyed. It is very important to accurately control the amount of power that is delivered to the target tissue to accurately control this temperature, thus protecting the patient.

5  Sensors 126, 128 provide this protection by measuring the RF current that is passed through the target tissue and the RF voltage applied across the tissue. These measurement signals are applied to their respective power measurement systems 132, 134 and to the differential sensor 130.

10  Power measurement systems 132, 134 generate feedback signals based on measurement signals provided by their respective sensors 126, 128 and the differential sensor 130. These feedback signals are used by microcontroller 102 and control systems 106 and 108 to control the operation of the RF power delivery system 100. Each power

15  measurement system 132, 134 preferably includes an analog multiplier, means for measuring the root-mean-squared (RMS) value of each analog measurement signal, and an analog-to-digital (A/D) converter. The analog multiplier provides a measure of the RF power applied to each electrode 26 by multiplying the RF current and voltage measured by the

20  sensors 126, 128. The RMS values of the measured current, voltage, and power are computed and then digitized by the A/D converter. These digitized measurement signals are then applied to the microcontroller 102 and the digitized power measurement is applied to the control systems 106, 108.

25  Temperature measurement system 136 generates digital feedback signals based on analog temperature measurement signals from the temperature sensors 42, 78, 80, 82. The digital temperature feedback signals are applied to microcontroller 102 and the control systems 106, 108.

The dual-channel RF power delivery system 100 has five different modes of operation, including SELF-TEST, STAND-BY, READY, RF ON, and RF OFF. When the power system is first turned on, the system enters the SELF-TEST mode. Various self-tests are performed in this

5      mode, including a microprocessor test, RAM read/write test, a ROM test, an RF power generation and measurement test, and a temperature measurement system test. When the various tests are successfully passed, the system enters the STAND-BY mode. If the test is not passed, an error message appears on the display.

10     In the STAND-BY mode, power is supplied for the various functions, but none of the functions is active. When the READY switch on the front panel 104 is pressed, the system enters the READY mode. In the READY mode, low-level RF signals are generated intermittently to allow impedance measurements to be made. The UP/DOWN POWER

15     switch allows the desired power level for each electrode 26 to be incremented or decremented by 0.1 watt. The power range is limited to 0-15 watts. The UP/DOWN TIMER switch allows the desired time duration for each electrode 26 to be incremented or decremented by 1 second. The maximum time duration is typically limited to 10 minutes.

20     In the READY mode, temperature measurements are taken from each thermocouple. The two stylet temperatures are read ten times per second and a filtered average is displayed on the front panel 104, which is updated once per second. The urethral and rectal temperatures are also read ten times per second and a filtered average of the urethral

25     temperature and a filtered maximum rectal temperature are displayed on the front panel 104. Impedance of the target tissue at the two electrodes 26 is measured by intermittently applying a low powered RF signal to each electrode and measuring the resulting RF voltage and RF

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current. The microcontroller 102 calculates the impedance by dividing the RF voltage by the RF current.

In the RF ON mode, RF power is generated and the measurement, control, display and timer functions are active. The RF ON mode is

5    activated either by depressing the foot switch or the RF ON/OFF switch. Depressing the STANDBY switch or the foot switch reactivates the STANDBY mode. The RF OFF mode is automatically activated when the selected time durations for both stylets have been reached, or if any of the measured temperatures exceed predefined limits.

10    Fig. 5 is a flow chart of the sequence of operations of the RF ON mode of the RF power delivery system 100 of the present invention. The user inputs the initial information in step 162. Initial information includes frequency, phase, power, and time duration for each RF signal. This information is typically entered using the keypad provided on the

15    front panel 104. In step 164, the initial information is received by microcontroller 102, which generates digital command signals that are sent to control systems 106, 108 and filters 122, 124.

In step 166, the two power delivery channels generate two independent RF signals, with each RF signal having a selected power

20    level, frequency, and phase. The RF power level is increased gradually toward the desired power level, at which time the RF signals are applied to their respective electrodes 26.

To protect the patient from receiving an excessive amount of RF energy, the RF power delivered to the target tissue is monitored by two

25    different methods. The RF power levels are monitored either directly or through their effects on the target and surrounding tissues as indicated by the various temperature measurements. The RF power is monitored directly in step 168. Sensors 126, 128 measure the RF currents and RF voltages at the two electrodes 26. The power delivered to the target

tissue is then calculated by the power measurement systems 132 and 134, as previously discussed.

Steps 170 and 172 may be performed simultaneously. In step 172, the power levels calculated by power measurement systems 132,

5      134 are compared with their respective selected power levels. The generated power levels are reduced if the measured power levels exceed their respective selected power levels. In step 170, RF power is terminated if the measured temperature of the target or the surrounding tissue exceeds a threshold temperature. RF power is delivered to the

10     target tissue for a time duration as selected by the user. In step 174, after the selected time duration has expired, the power system enters the RF OFF mode.

The dual-channel RF power delivery system 100 of the present invention provides numerous advantages over prior art power delivery

15     systems. The power delivery system 100 performs a battery of self-tests, including a test of each waveform generator 110, 112 by loading the generator with an internal test load. Precision reference voltage sources (not shown) are provided which can be used for calibrating the thermocouples. This test is implemented through a multiplexing scheme

20     in which each thermocouple is individually calibrated using the reference voltages.

The use of multiplexers also allows temperature information to be easily obtained across the patient isolation barrier. An isolation barrier, such as a transformer-coupled or optically-coupled isolation amplifier, is

25     usually required between a patient and a microcomputer. The use of the multiplexer arrangement avoids the need for separate isolation amplifiers for each thermocouple.

Another significant advantage of the power delivery system 100 of the present invention is the availability of a combined monopolar and

bipolar mode. In the monopolar mode, the same RF signal is applied to each electrode 26 and current flows from the electrodes to an indifferent electrode placed on the patient's back. The two RF signals are at the same power level, frequency and phase. Therefore, the two electrodes

5    26 are at the same voltage levels and no current flows between them. Current only flows between each electrode and the indifferent electrode on the patient's back. However, by changing the power level, frequency or phase of one of the RF signals, a voltage is created across the electrodes 26 and current flows between them. This provides bipolar

10   ablation in combination with monopolar ablation. Differential sensor 130 measures the difference in the current flows from the two electrodes 26 to the indifferent electrode. Bipolar ablation in combination with monopolar ablation allows a larger tissue volume to be ablated without increasing the RF energy applied to the patient. Figure 6 is a schematic

15   diagram of the lesion volumes provided by monopolar, bipolar and combined monopolar and bipolar RF ablation.

The results of laboratory tests in which one of the RF signals was varied in phase, frequency, and phase and frequency are shown in Table 1. Turkey breasts were used as the target tissue.

|  |  | Total Power (Watts) | The Power Of The First Electrode | The Power Of The Second Electrode | Time (Min) | Lesion Volume |
|---|---|---|---|---|---|---|
| 20 | 1. One Supply | 8.2 | 4.1 | 4.1 | 5 | 1653 |
|  | 2. Two Power Supplies and Phase Difference | 4.1 (each supply) | 4.1 | 4.1 | 5 | 3600 |
| 25 | 3. Two Power Supplies and Frequency Difference | 4.1 (each supply) | 4.1 | 4.1 | 5 | 2135 |

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SUBSTITUTE SHEET (RULE 26)

| 4. Two Power Supplies and Phase and Frequency Difference | 4.1 (each supply) | 4.1 | 4.1 | 5 | 45821 |
|---|---|---|---|---|---|

### TABLE 1

In the first case, the same RF signal of 4.1 watts was applied to each electrode 26 for a total RF power level of 8.2 watts. In the second, third, and fourth cases, each RF signal had a power level of 4.1 watts, but the frequency, phase and frequency and phase of one of the RF signals were varied. In the second case, the two RF signals were out of phase. In the third case, one RF signal had a frequency of 460 KHz and the other RF signal had a frequency of 480 KHz. In the fourth case, one RF signal had a frequency of 460 KHz the other RF signal had a frequency of 480 KHz and the RF signals were out of phase. In all four cases, the power was delivered to the target tissues for 5 minutes. In the fourth case, with the two RF signals out of phase and at different frequencies, the lesion volume was about three times the volume in the first case, which issued identical RF signals.

From the foregoing, it will be appreciated that the present invention represents a significant advance in the field of RF ablation devices. Although several preferred embodiments of the invention have been shown and described, it will be apparent that other adaptations and modifications can be made without departing from the spirit and scope of invention. Accordingly, the invention is not to be limited, except as by the following claims.

WHAT IS CLAIMED IS:

1. A dual-channel radiofrequency (RF) power delivery system for monopolar and bipolar RF ablation of a target tissue, comprising:

    a first RF power delivery channel for generating a first RF signal

5            which is to be applied to a first electrode, the first RF signal having a first power level, frequency, and phase;

    a second RF power delivery channel for generating a second RF signal which is to be applied to a second electrode, the second RF signal having a second power level, frequency,

10            and phase;

    wherein the target tissue is ablated by inserting the first and second electrodes into the target tissue with the first and second power levels, frequencies and phases selected to provide a desired combination of monopolar and bipolar RF
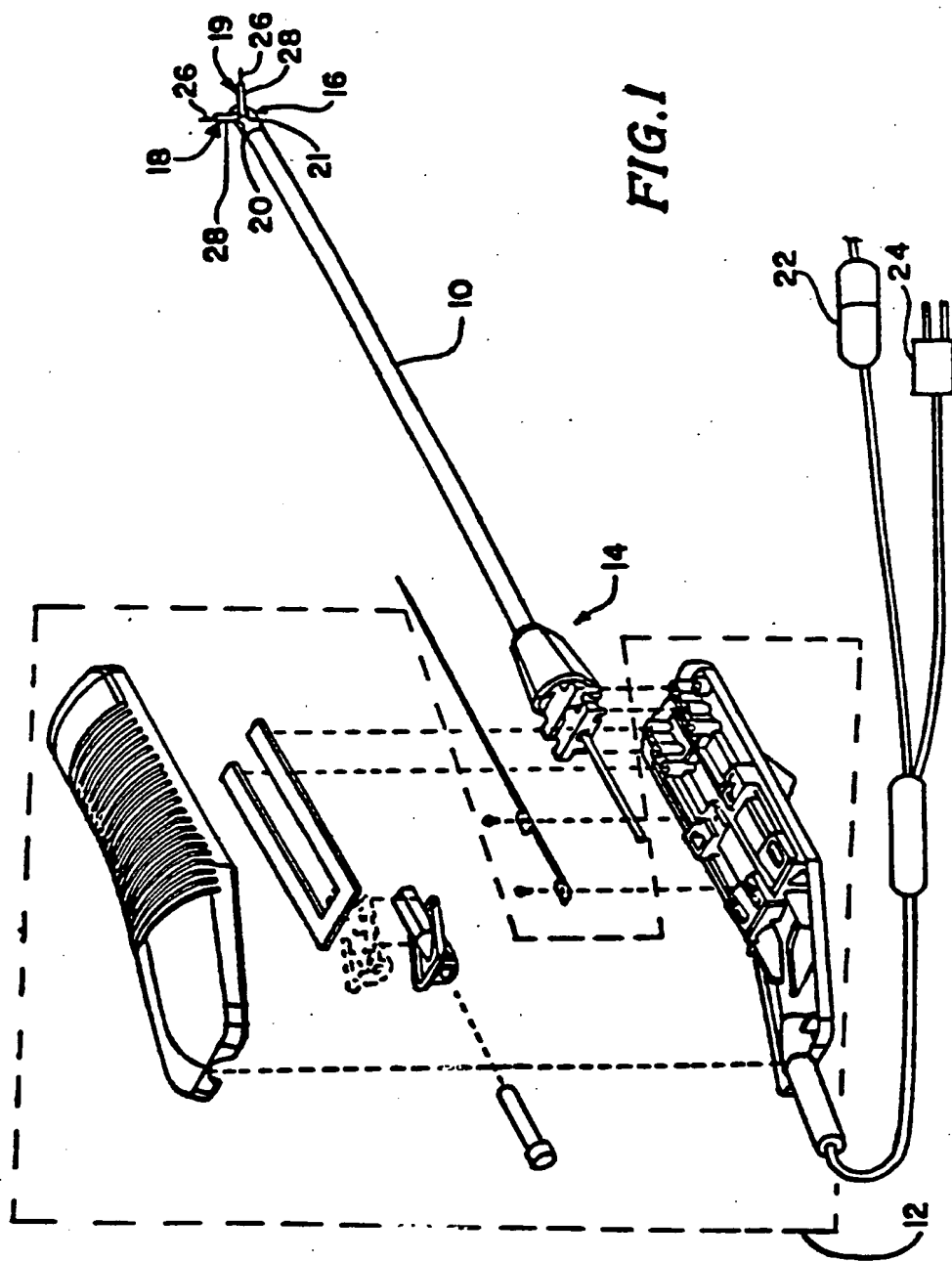
15            ablation.

2. The dual-channel RF power delivery system as set forth in Claim 1, and further including a differential sensor connected to the first and second power delivery channels for monitoring the difference between the first and second power levels to control the relative

20 amounts of monopolar and bipolar ablation.

3. The dual-channel RF power delivery system as set forth in Claim 1, and further including temperature measurement means for measuring the target and surrounding tissue temperatures.

4. The dual-channel RF power delivery system as set forth in

25 Claim 1, and further including means for monitoring the impedances of the target tissue.

5. A method of ablating a target tissue using both monopolar and bipolar radio frequency (RF) ablation, comprising the steps of:

    inserting first and second electrodes into a target tissue;

applying a first RF signal having a first power level, frequency, and
phase to the first electrode;

applying a second RF signal having a second power level,
frequency, and phase to the second electrode; and

5     maintaining the power levels of the first and second RF signals for
predetermined time durations;

wherein the first and second power levels, frequencies, and
phases are selected to provide a desired combination of
monopolar and bipolar RF ablation of the target tissue.

10     6.     The method as set forth in Claim 5, and further including
the step of monitoring the difference between the first and second power
levels to control the relative amounts of monopolar and bipolar ablation.

7.     The method as set forth in Claim 5, and further including
the step of measuring the target and surrounding tissue temperatures.

15     8.     The method as set forth in Claim 5, and further including
the step of monitoring the impedances of the target tissue.

9.     The method as set forth in Claim 5, wherein the phase of
the first RF signal is different from the phase of the second RF signal by
an amount less than 180 degrees.

20     10.     The method as set forth in Claim 5, and further including
the step of monitoring at least one temperature of a body organ in the
vicinity of the target tissue and terminating the application of the first
and second RF signals when the monitored temperature exceeds a
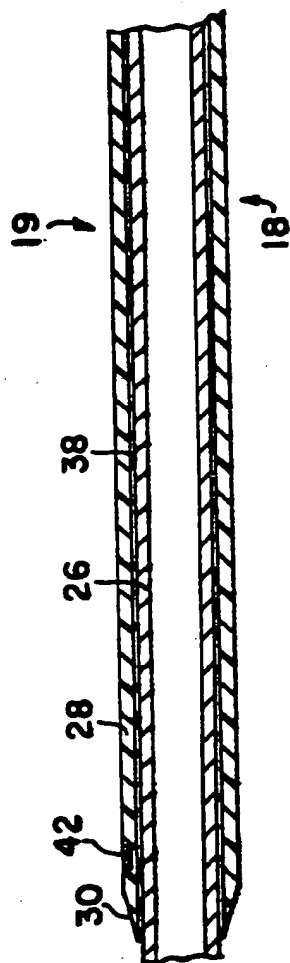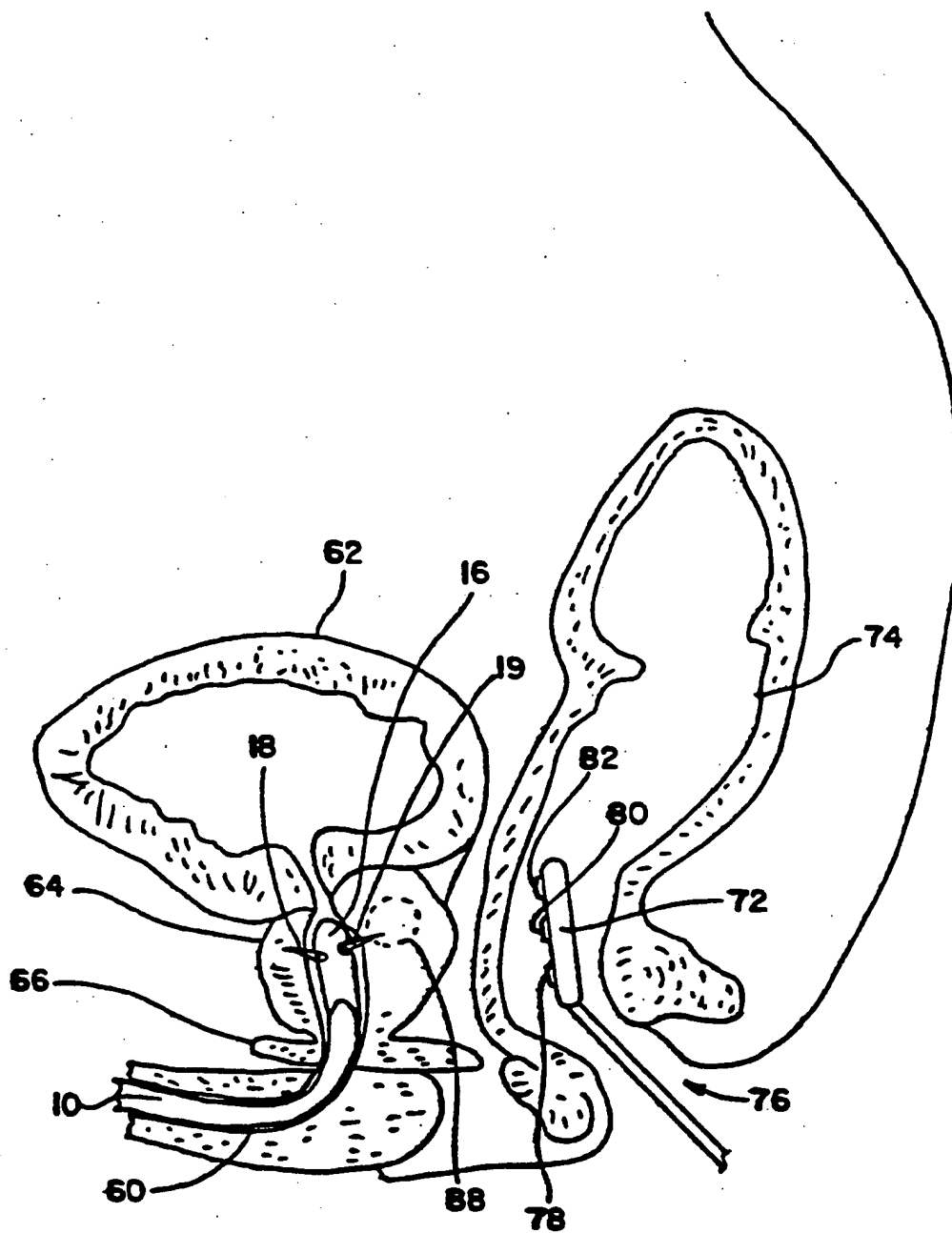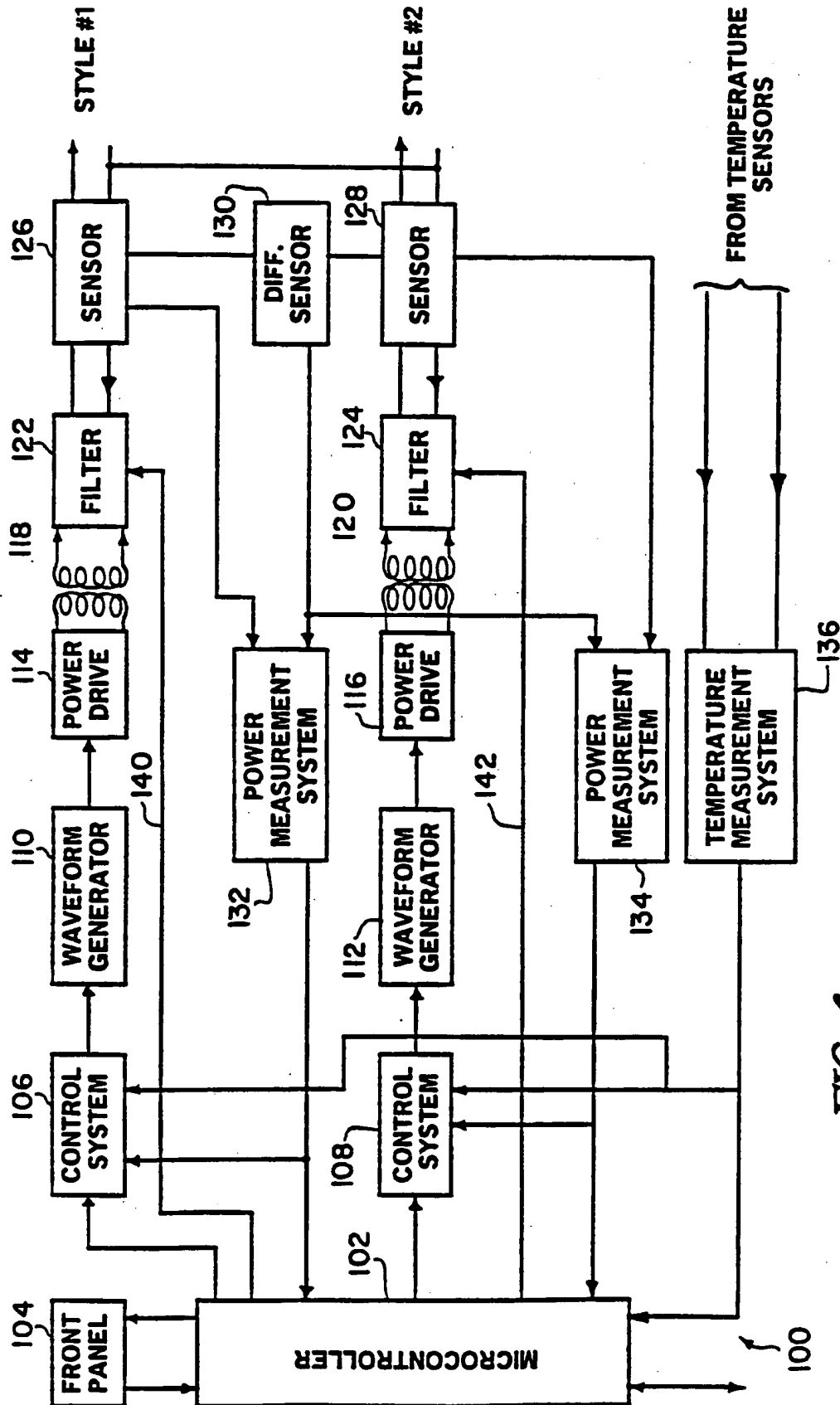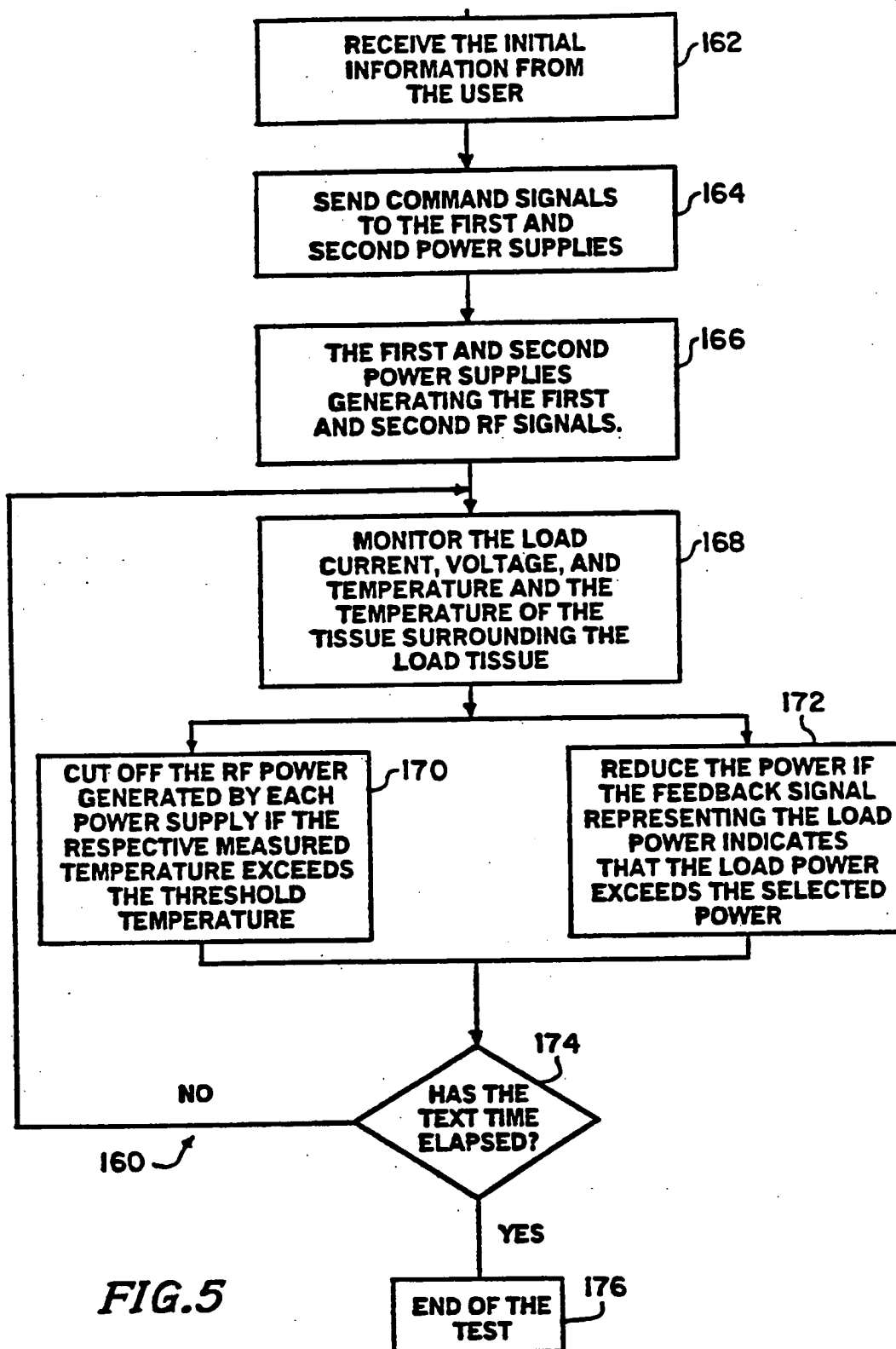predetermined safe organ temperature.

*FIG.1*

FIG.2

**FIG.3**

FIG. 4

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                    ┌─────────────────────────┐
                    │   RECEIVE THE INITIAL    │ ┌162
                    │   INFORMATION FROM       │
                    │       THE USER           │
                    └─────────────────────────┘
                               │
                               ▼
                    ┌─────────────────────────┐
                    │  SEND COMMAND SIGNALS    │ ┌164
                    │    TO THE FIRST AND      │
                    │  SECOND POWER SUPPLIES   │
                    └─────────────────────────┘
                               │
                               ▼
                    ┌─────────────────────────┐
                    │   THE FIRST AND SECOND   │ ┌166
                    │     POWER SUPPLIES       │
                    │  GENERATING THE FIRST    │
                    │  AND SECOND RF SIGNALS.  │
                    └─────────────────────────┘
                               │
                               ▼
                    ┌─────────────────────────┐
                    │    MONITOR THE LOAD      │ ┌168
                    │ CURRENT, VOLTAGE, AND    │
                    │  TEMPERATURE AND THE     │
                    │   TEMPERATURE OF THE     │
                    │ TISSUE SURROUNDING THE   │
                    │      LOAD TISSUE         │
                    └─────────────────────────┘
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                                                                       172
┌──────────────────────────┐              ┌──────────────────────────┐
│  CUT OFF THE RF POWER     │ ┌170         │  REDUCE THE POWER IF      │
│  GENERATED BY EACH        │              │  THE FEEDBACK SIGNAL      │
│  POWER SUPPLY IF THE      │              │  REPRESENTING THE LOAD    │
│  RESPECTIVE MEASURED      │              │  POWER INDICATES          │
│  TEMPERATURE EXCEEDS      │              │  THAT THE LOAD POWER      │
│  THE THRESHOLD            │              │  EXCEEDS THE SELECTED     │
│  TEMPERATURE              │              │  POWER                    │
└──────────────────────────┘              └──────────────────────────┘
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                              174
                     ◇
              NO    ╱ HAS THE  ╲
          ────────── TEXT TIME  
         │          ╲ ELAPSED? ╱
    160 ┘            ◇
                       │
                      YES
                       │
                       ▼
                 ┌──────────────┐ 176
                 │  END OF THE  │
                 │     TEST     │
                 └──────────────┘
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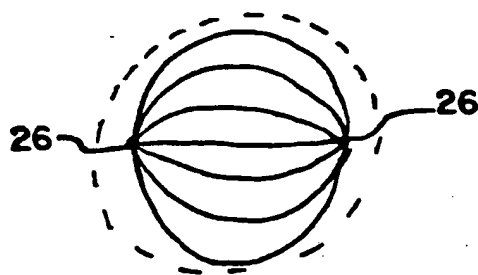
*FIG.5*

**MONOPOLAR RF ABLATION**

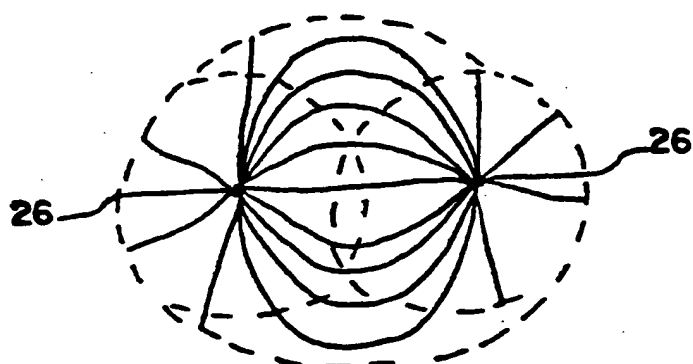**BIPOLAR RF ABLATION**

**COMBINED MONOPOLAR & BIPOLAR RF ABLATION**

*FIG. 6*

6 / 6

| INTERNATIONAL SEARCH REPORT | International application No.<br>PCT/US95/03785 |
|---|---|

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6)  :A61B 17/39
US CL  :604/22

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

  U.S.  :  601/2;. 604/19-22, 53, 164, 280;  606/32, 39, 45;  607/96, 101, 102, 113, 115, 116, 138, 156

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

  NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

  NONE

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | WO, A,  92/10142 (MAKOWER) 25 June 1992. See entire patent. | 1-10 |
| Y | US, A, 4,950,267 (ISHIHARA ET AL.) 21 August 1990. See entire document. | 1-10 |

☐ Further documents are listed in the continuation of Box C.    ☐  See patent family annex.

| * | Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
|---|---|---|---|
| "A" | document defining the general state of the art which is not considered to be part of particular relevance | | |
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| Date of the actual completion of the international search<br><br>30 APRIL 1995 | Date of mailing of the international search report<br><br>01 JUN 1995 |
|---|---|
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No.  (703) 305-3230 | Authorized officer<br><br>MANUEL MENDEZ<br>Telephone No.  (703) 308-2221 |

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